

Please type a plus sign (+) inside this box



PTO/SB/05 (4/98)

Approved for use through 09/30/2000. OMB 0651-0032
Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. 003543.P002

First Inventor or Application Identifier Hai Bui

Title CONSTANT OCULAR PRESSURE ACTIVE INFUSION SYSTEM

Express Mail Label No. EL236786540US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)
2. ☒ Specification [Total Pages 23]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 1]
4. Oath or Declaration [Total Pages 2]
 - a. ☒ Newly executed (original copy)
 - b. ☐ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR §§ 1.63(d)(2) and 1.33(b).

5. ☐ Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. ☒ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☒ Information Disclosure Statement (IDS)/PTO - 1449 ☒ Copies of IDS Citations
11. ☐ Preliminary Amendment
12. ☐ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. ☐ *Small Entity Statement(s) ☐ Statement filed in prior application, Status still proper and desired
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other:

*NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No:

Prior application Information: Examiner

Group/Art Unit:

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

☐ Customer Number of Bar Code Label

(Insert Customer No. or Attach bar code label here)

or ☒ Correspondence address below

Name BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Address 12400 Wilshire Boulevard, Seventh Floor

City Los Angeles State California Zip Code 90025

Country U.S.A. Telephone (714) 557-3800 Fax (714) 557-3347

Name (Print/Type) Ben J. Yorks, Reg. No. 33,609

Signature

Ben Yorks

Date 05/21/99

Burden Hour Statement This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

PTO/SB/16 (1-99)
Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(e)) – SMALL BUSINESS CONCERN	Docket Number (Optional) 003543.P002
--	--

Applicant, Patentee, or Identifier: Hai Rui

Application or Patent No.: _____

Filed or issued: May 21, 1999

Title: CONSTANT OCULAR PRESSURE ACTIVE INFUSION SYSTEM

I hereby state that I am

☒ the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN Butvision

ADDRESS OF SMALL BUSINESS CONCERN 9436 Kiwi Circle
Fountain Valley, California 92708

I hereby stated that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

☒ the specification filed herewith, with title as listed above.

☐ the application identified above.

☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who could not qualify as a an independant inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a non-profit organization under 37 CFR 1.9(e).

Each such person, concern or organization having any rights in the invention is listed below:

☒ No such person, concern, or organization exists.

☐ Each such person, concern or organization is listed below.*


Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities (37 CFR 1.9(e)).

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING: Hai Rui

TITLE OF PERSON OTHER THAN OWNER: President

ADDRESS OF PERSON SIGNING: 9436 Kiwi Cir., Fountain Valley, CA 92708

SIGNATURE:  DATE: 5/21/99

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Our File No.: 003543.P002
Express Mail No.: EL236786540US

UNITED STATES PATENT APPLICATION

FOR

CONSTANT OCULAR PRESSURE ACTIVE INFUSION SYSTEM

INVENTOR: Hai Bui

PREPARED BY:

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN
12400 Wilshire Blvd., 7th Floor
Los Angeles, CA 90025-1026
(714) 557-3800

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

5 The present invention relates to an irrigation system for a medical device such as a phacoemulsification handpiece.

2. BACKGROUND INFORMATION

10

 The lens of an eye can be removed in a procedure commonly referred to as phacoemulsification ("phaco"). In a phaco procedure an ultrasonically driven tip is inserted through a small incision in the cornea and used
15 to emulsify the lens. The tip extends from a handpiece that is held by a surgeon. The tip is coupled to an irrigation system that supplies an irrigation fluid to the surgical site. The tip is also coupled to an aspiration system that aspirates the irrigation fluid and
20 the emulsified lens. The irrigation fluid provides a medium to remove the emulsified lens. Additionally, the irrigation fluid provides a medium to transfer heat generated by the ultrasonically driven tip.

 When performing a phaco procedure emulsified lens
25 tissue may occlude the aspiration line. The occlusion may increase the downstream vacuum pressure of the aspiration line. If the occlusion becomes dislodged the

cornea will be exposed to the increased vacuum pressure. This large instantaneous vacuum pressure may cause the cornea to collapse. There have been developed various devices and systems for preventing a cornea collapse due to an occlusion in the aspiration line. For example, U.S. Patent No. 5,106,367 issued to Ureche, et al. discloses a vacuum surge suppressor that limits the transient flow during a vacuum surge by increasing the resistance of the aspiration line.

Most phaco systems address the issue of occlusion and control of intraocular pressure with devices, sensors etc. in the aspiration system. The aspiration system is downstream from the eye. The control of pressure and flowrate in the eye is therefore somewhat limited. Such a system is similar to controlling the flow of water through a stream with a dam located at the end of the stream. Any input from a downstream dam will have a delayed and possibly attenuated effect on the upstream conditions. It would be desirable to integrate control and safety features in the upstream irrigation systems.

U.S. Patent Nos. 3,812,855 and 3,920,014 issued to Banko disclose an irrigation system that contains a plurality of solenoid actuated valves which control the flow of an irrigation fluid to a surgical site. Each valve may have an adjustable needle to vary the flowrate and corresponding pressure of the irrigation fluid. The Banko system provides no intelligence as to an occluded

condition or any type of feedback loop that can be used
to control the intraocular pressure. It would be
desirable to provide an irrigation system that can
control the intraocular pressure and provide various
5 safety features for an ophthalmic surgical procedure.

SUMMARY OF THE INVENTION

One embodiment of the present invention is an irrigation system for a medical device. The irrigation system may include a pump that can pump irrigation fluid from a reservoir through an irrigation line. The system may further have a controller coupled to the pump and an accumulator pressure sensor that senses the pressure of the irrigation line. The controller can vary the speed of the pump in response to a change in the line pressure to control the irrigation line pressure. Additionally, the controller can monitor the fluidic resistance of the system by determining the pump speed and corresponding flowrate of the pump. The controller can provide one or more safety output signals if the fluidic resistance exceeds a threshold value(s).

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic of an embodiment of a medical system of the present invention.

DETAILED DESCRIPTION

Referring to the drawings more particularly by reference numbers, Figure 1 shows an embodiment of a medical system 10 of the present invention. The system 10 may include a medical device 12 that is coupled to an irrigation system 14 and an aspiration system 16. The medical device 12 may include an ultrasonically driven tip 18 that extends from a handpiece 20. The handpiece 20 is typically held by a surgeon who inserts the tip 18 through an incision in a cornea (not shown). The irrigation system 14 provides an irrigation fluid to the tip 18 and the surgical site. The aspiration system 16 removes the irrigation fluid and any detached tissue from the surgical site. Although a phaco handpiece is shown and described, it is to be understood that the system 10 may contain another type of medical device such as a guillotine cutter.

The aspiration system 16 may include an aspiration line 22 that is coupled to an aspiration pump 24 and the tip 18 of the medical device 12. The pump 24 may pull irrigation fluid and tissue from the surgical site to a depository 26. By way of example, the aspiration pump 24 may be a non-invasive peristaltic pump. The aspiration system 16 may include a pressure sensor 27 that senses the pressure of the aspiration line 22.

The irrigation system 14 may include an irrigation pump 28 that is coupled to an irrigation line 30 and an irrigation fluid reservoir 32. The reservoir 32 may be an IV bottle full of irrigation fluid as is known in the art. The irrigation pump 28 may be a non-invasive peristaltic pump that generates a flow of irrigation fluid through the line 30 from the reservoir 32 to the medical device 12.

The irrigation system 14 may further have an accumulator pressure sensor 34 coupled to the irrigation line 30. The accumulator pressure sensor 34 may be coupled to a controller 36. The controller 36 may also be coupled to the pump 28. The controller 36 may include a microprocessor, memory, etc. that can receive input signals, process the signals in accordance with a software routine(s) and provide output signals.

The accumulator pressure sensor 34 may include a flexible membrane 38 that separates a first chamber 40 from a second chamber 42. The first chamber 40 is in fluid communication with the irrigation line 30. The second chamber 42 is in fluid communication with a pressure transducer 44 of the controller 36.

During normal operation, the membrane 38 will deflect with variations in pressure of the irrigation line 30 and the first chamber 40. Deflection of the membrane 38 will change the volume of the second chamber 42 and the corresponding pressure therein. The change in pressure

within the irrigation line 30 is sensed by the pressure transducer 44 of the controller 36.

The accumulator pressure sensor 34 provides multiple functions. The first chamber 40 provides a reservoir of pressurized fluid for the system and functions as a fluidic capacitor that can maintain the intraocular pressure of the eye. The flexible membrane 38 and first chamber 40 can also filter pressure pulsations created by the pump 28. Additionally, the flexible membrane 38 provides a non-invasive means for sensing the pressure within the irrigation line 30. The system may include an accumulator (not shown) that provides additional capacitance for the second chamber 42. The additional accumulator may reduce the sensitivity of the pressure sensor 34 and allow greater volume of irrigation fluid to be stored in the first chamber 40.

The irrigation system 14 may include a valve 46 that can be switched by the controller 36 between an on position and an off position to control the flow of irrigation fluid through the irrigation line 30. The system 10 may also have a valve 48 that couples the irrigation system 14 to the aspiration system 16. The valve 48 can be opened to reflux or vent the aspiration line 30.

In operation, the controller 36 may receive an input signal from the transducer 44 that corresponds to the pressure within the irrigation line 30. The controller

36 may compare the actual pressure signal with a desired pressure signal. If the actual pressure deviates from the desired pressure the controller 36 may provide an output signal(s) to vary the speed of the pump 28. To prevent a constant switching of the pump 28 the controller 36 may determine whether the actual pressure is within a desired range of pressures. If the actual pressure is within the desired range the controller 36 may not vary the speed of the pump 28. If the actual pressure is outside the desired range the controller 36 can vary the pump speed, accordingly.

By way of example, if the valve 46 is open and the actual pressure is greater than the desired range, the controller 36 can decrease the speed of the pump 28 to reduce the irrigation pressure. Likewise, if the actual pressure is less than the desired range the controller 36 can increase the speed of the pump 28. If the valve 46 is closed the irrigation pressure can be decreased by reversing the direction of the pump 28 to pump fluid out of the accumulator pressure sensor 34. The controller 36, sensor 34 and pump 28 can thus be used as a closed loop feedback system to control the intraocular pressure of an eye during a surgical procedure.

The irrigation system 14 may have a speed sensor 50 that can provide a feedback signal to the controller 36 which corresponds to the speed of the pump 28. The speed sensor 50 may be an optical encoder (not shown) and

accompanying circuitry coupled to the output shaft of the pump motor (not shown). Pumps 28 are positive displacement type pumps. In a normal operating range the flowrate generated by the pump 28 is linearly

5 proportional to the pump speed. The controller 36 can thus determine the flowrate from the speed of the pump 28 with one or more relatively simple calculations.

The controller 36 can calculate the volume of fluid pumped through the irrigation line 30 by multiplying the
10 flowrate with the pumping time. The controller 36 can predict when the reservoir 32 is being depleted by comparing the calculated fluid volume with a threshold value. The threshold value may correspond to a predetermined volume of the reservoir 32. When the
15 calculated volume is greater than the threshold value the controller 36 can activate a visual and/or audio indicator 52 to warn the operator to replace the reservoir 32.

Additionally, the ability to sense the instantaneous
20 irrigation flowrate enables the controller 36 to maintain a constant intraocular pressure by compensating for the pressure drop in the irrigation circuit. With a known irrigation source resistance, the controller 36 can easily calculate and compensate for the pressure loss
25 using the basic fluid equation: $\text{Pressure} = \text{Flow} \times \text{Resistance}$. The irrigation source resistance can be determined in the design phase using both theoretical and

empirical methods. This typical value can be stored in the controller 36 as constant. However, for better results, the control system can accurately determine the irrigation resistance for each specific setup by measuring the flowrate at a specific pressure with irrigation free flow and calculate the resistance.

By sensing the flowrate the controller 36 can also determine whether there is an occlusion in the aspiration system 16. An occlusion will increase the fluidic resistance of the entire system. The controller 36 can calculate the fluidic resistance by dividing the differential pressure across the system by the flowrate. The calculated actual fluidic resistance can be compared to a threshold resistance value. If the actual resistance is greater than the threshold the controller 36 may activate a visual and/or audio indicator 54 to warn the surgeon that an occlusion may exist in the system.

If the actual resistance is greater than the threshold value, the controller 36 may also change the speed of the aspiration pump 24 to alter the rate of vacuum rise within the aspiration line 22. The controller 36 may reduce or terminate the power to the medical device 12 to prevent undesirable heating of tissue by the ultrasonically driven tip 18. Power reduction may be accomplished by decreasing the power level and or applying the power in an intermittent manner (i.e.

pulse, burst, ect.). The reduction or termination of power may correspond to different resistance thresholds. By way of example, when the actual resistance exceeds a first threshold the controller 36 may reduce power to the medical device 12. When the actual resistance is greater than a higher threshold the controller 36 may actually turn the device off.

The threshold resistance value(s) can be normalized with the actual resistance of the system by either calculating the system resistance, or measuring the resistance when the system is set up and the device is inserted into a test chamber . The system resistance can be calculated by allowing irrigation fluid to flow through the irrigation line, test chamber and aspiration line, and then determining the resistance by dividing the sensed differential pressure by the measured flowrate. The flowrate can be determined from the speed of the pump 28. The differential pressure can be determined from the pressures sensed by sensors 27 and 34.

While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative of and not restrictive on the broad invention, and that this invention not be limited to the specific constructions and arrangements shown and described, since various other modifications may occur to those ordinarily skilled in the art.

003543.P002
Express Mail No.: EL236786540US

CLAIMS

What is claimed is:

1 1. An irrigation system for a medical device,
2 comprising:
3 an irrigation reservoir;
4 a pump coupled to said irrigation reservoir;
5 an irrigation line coupled to said pump;
6 a pressure sensor that senses a pressure within said
7 irrigation line;
8 an accumulator that stores irrigation fluid; and,
9 a controller that is coupled to said pressure sensor
10 and said pump to control the pressure within said
11 irrigation line.

1 2. The irrigation system of claim 1, wherein said
2 pressure sensor includes a flexible membrane that
3 separates a first chamber from a second chamber, said
4 first chamber being in fluid communication with said
5 irrigation line, said second chamber being in fluid
6 communication with a pressure transducer of said
7 controller.

1 3. The irrigation system of claim 1, further
2 comprising a valve coupled to said irrigation line and
3 said controller.

1 4. The irrigation system of claim 1, wherein said
2 controller controls a speed of said pump and a flowrate
3 through said irrigation line.

1 5. The irrigation system of claim 4, wherein said
2 controller varies said pump speed in response to a
3 variation in the irrigation line pressure sensed by said
4 pressure sensor.

1 6. The irrigation system of claim 1, wherein said
2 controller can determine a flowrate generated by said
3 pump.

1 7. The irrigation system of claim 6, wherein said
2 controller determines an actual fluidic resistance from
3 the flowrate and provides an output signal if the actual
4 fluidic resistance is greater than a threshold value.

1 8. The irrigation system of claim 6, wherein said
2 controller determines an actual volume of irrigation
3 fluid pumped by said pump from the flowrate and provides
4 an output signal if the actual volume of irrigation fluid
5 is greater than a threshold value.

6 9. An irrigation system for a medical device,
7 comprising:
8 an irrigation reservoir;
9 a pump coupled to said irrigation reservoir, said
10 pump generates a flowrate;
11 an irrigation line coupled to said pump; and,
12 a controller that can determine the flowrate
13 generated by said pump.

1 10. The irrigation system of claim 9, wherein said
2 pump has a speed sensor coupled to said controller.

1 11. The irrigation system of claim 9, wherein said
2 controller determines an actual fluidic resistance from
3 the flowrate and provides an output signal if the actual
4 fluidic resistance is greater than a threshold value.

1 12. The irrigation system of claim 9, wherein said
2 controller determines an actual volume of irrigation
3 fluid pumped by said pump from the flowrate and provides

4 an output signal if the actual volume of irrigation fluid
5 is greater than a threshold value.

1 13. A medical system, comprising:

2 an irrigation system that includes;

3 an irrigation reservoir;

4 an irrigation pump that is coupled to said irrigation
5 reservoir;

6 an irrigation line coupled to said pump;

7 a pressure sensor that senses a pressure within said
8 irrigation line;

9 an accumulator that stores irrigation fluid;

10 a controller that is coupled to said pressure sensor
11 and said irrigation pump to control the pressure within
12 said irrigation line;

13 an aspiration system that includes;

14 an aspiration pump;

15 an aspiration line coupled to said aspiration pump;

16 an aspiration pressure sensor that senses a vacuum
17 pressure within said aspiration line;

18 a medical device that is coupled to said irrigation
19 line and said aspiration line.

1 14. The medical system of claim 13, wherein said
2 pressure sensor includes a flexible membrane that
3 separates a first chamber from a second chamber, said
4 first chamber being in fluid communication with said

5 irrigation line, said second chamber being in fluid
6 communication with a pressure transducer of said
7 controller.

1 15. The medical system of claim 13, further
2 comprising a valve coupled to said irrigation line and
3 said controller.

1 16. The medical system of claim 13, wherein said
2 controller controls a speed of said irrigation pump and a
3 flowrate through said irrigation line.

1 17. The medical system of claim 16, wherein said
2 controller varies said pump speed in response to a
3 variation in the irrigation line pressure sensed by said
4 pressure sensor.

1 18. The medical system of claim 13, wherein said
2 controller can determine a flowrate generated by said
3 irrigation pump.

1 19. The medical system of claim 18, wherein said
2 controller determines an actual fluidic resistance from
3 the flowrate and provides an output signal if the actual
4 fluidic resistance is greater than a threshold value.

1 20. The medical system of claim 18, wherein said
2 controller determines an actual volume of irrigation
3 fluid pumped by said pump from the flowrate and provides
4 an output signal if the actual volume of irrigation fluid
5 is greater than a threshold value.

1 21. The medical system of claim 19, wherein said
2 controller reduces a power of said medical device if the
3 actual fluidic resistance is greater than a device
4 threshold value.

1 22. The medical system of claim 19, wherein said
2 controller changes a speed of said aspiration pump if the
3 actual fluidic resistance is greater than a pump
4 threshold value.

1 23. The medical system of claim 13, further
2 comprising a valve that is coupled to said irrigation
3 line and said aspiration line.

1 24. A method for controlling a pressure of an
2 irrigation line of a medical irrigation system,
3 comprising:

4 sensing a variation in the irrigation line pressure
5 with a pressure sensor; and,

6 varying the speed of a pump that is coupled to the
7 irrigation line in response to the sensed variation in
8 irrigation line pressure.

1 25. The method of claim 17, closing the irrigation
2 line and reversing a direction of the pump.

1 ~~26.~~ A method for determining a flowrate through an
2 irrigation line of a medical system, comprising:
3 sensing a speed of a pump that generates a flowrate
4 of the irrigation fluid;
5 determining the flowrate from the pump speed.

1 27. The method of claim 26, determining an actual
2 fluidic resistance from the flowrate.

1 28. The method of claim 27, generating an output
2 signal if the fluidic resistance is greater than a
3 threshold value.

1 29. The method of claim 27, reducing a power of a
2 medical device if the actual fluidic resistance is
3 greater than a threshold value.

1 30. The method of claim 27, changing the speed of an
2 aspiration pump if the actual fluidic resistance is
3 greater than a threshold value.

1 31. The method of claim 27, determining an actual
2 volume of irrigation fluid pumped by the pump.

1 32. The method of claim 31, generating an output
2 signal if the actual volume of irrigation fluid is
3 greater than a threshold value.

ABSTRACT OF THE DISCLOSURE

An irrigation system for a medical device. The irrigation system may include a pump that can pump
5 irrigation fluid from a reservoir through an irrigation line. The system may further have a controller coupled to the pump and an accumulator pressure sensor that senses the pressure of the irrigation line. The controller can vary the speed of the pump in response to
10 a change in the line pressure to control the irrigation line pressure. Additionally, the controller can monitor the fluidic resistance of the system by determining the pump speed and corresponding flowrate of the pump. The controller can provide one or more safety output signals
15 if the fluidic resistance exceeds a threshold value(s).

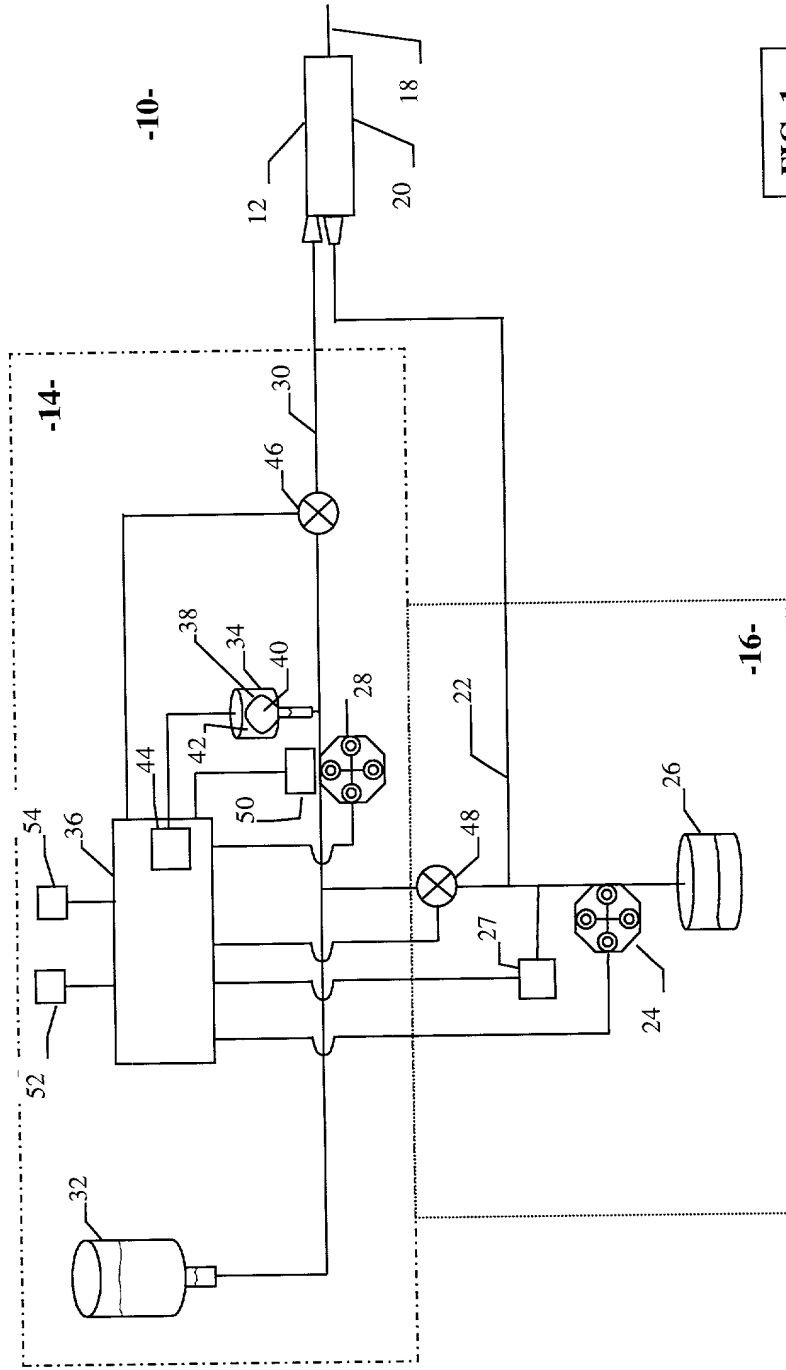


FIG. 1.

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or any original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CONSTANT OCULAR PRESSURE ACTIVE INFUSION SYSTEM

the specification of which ☒ is attached hereto.

☐ was filed on _____ as _____

United States Application Number _____

or PCT International Application Number _____

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above. I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, and that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

APPLICATION NUMBER	COUNTRY (OR INDICATE IF PCT)	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> No <input type="checkbox"/> Yes
			<input type="checkbox"/> No <input type="checkbox"/> Yes
			<input type="checkbox"/> No <input type="checkbox"/> Yes

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

APPLICATION NUMBER	FILING DATE
60/086,283	May 21, 1998

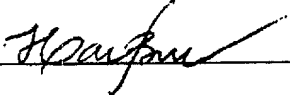
I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NUMBER	FILING DATE	STATUS (ISSUED, PENDING, ABANDONED)

I hereby appoint BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP, a firm including: William E. Alford, Reg. 37,764; Farzad E. Amini, Reg. No. 42,261; Aloysius T. C. AuYeung, Reg. No. 35,432; William Thomas Babbitt, Reg. No. 39,591; Carol F. Barry, 41,600; Jordan Michael Becker, Reg. No. 39,602; Bradley J. Bereznak, Reg. No. 33,474; Michael A. Bernadicou, Reg. No. 35,934; Roger W. Blakely, Jr., Reg. No. 25,831; Gregory D. Caldwell, Reg. No. 39,926; Lawrence M. Cho, Reg. No. 39,942; Yong S. Choi, Reg. No. 43,324; Thomas M. Coester, Reg. No. 39,637; Roland B. Cortes, Reg. No. 39,152; Barbara Bokanov Courtney, Reg. No. P42,442; William Donald Davis, Reg. No. 38,428; Michael Anthony DeSanctis, Reg. No. 39,957; Daniel M. De Vos, Reg. No. 37,813; Tarek N. Fahmi, Reg. No. P41,402; James Y. Go, Reg. No. 40,621; Richard Leon Gregory, Jr., P42,607; Dinu Gruia, Reg. No. 42,996; David R. Halverson, Reg. No. 33,395; Thomas A. Hassing, Reg. No. 36,159; James A. Henry, Reg. No. 41,064; Willmore F. Holbrow III, Reg. No. P41,845; George W. Hoover II, Reg. No. 32,992; Eric S. Hyman, Reg. No. 30,139; Dag H. Johansen, Reg. No. 36,172; William W. Kidd, Reg. No. 31,772; Tim L. Kitchen, Reg. No. P41,900; Michael J. Mallis, Reg. No. 36,391; Paul A. Mendonsa P42,879; Darren J. Milliken, P42,004; Thanh V. Nguyen, Reg. No. 42,034; Kimberley G. Nobles, Reg. No. 38,255; Michael A. Proksch P43,021; Babak Redjaian, Reg. No. 42,096; James H. Salter, Reg. No. 35,668; William W. Schaal, Reg. No. 39,018; James C. Scheller, Reg. No. 31,195; Anand Sethuraman, Reg. No. 43,351; Charles B. Shemwell, Reg. No. 40,171; Maria McCormack Sobrino, Reg. No. 31,639; Stanley W. Sokoloff, Reg. No. 25,128; Allan T. Sponseller, Reg. No. 38,318; Geoffrey T. Staniford, P43,151; Judith A. Szepesi, Reg. No. 39,393; Vincent P. Tassinari, Reg. No. 42,179; Edwin H. Taylor, Reg. No. 25,129; George G. C. Tseng, Reg. No. 41,355; Lester J. Vincent, Reg. No. 31,460; John Patrick Ward, Reg. No. 40,216; Stephen Warhola, P43,237; Charles T. J. Weigell, Reg. No. 43,398; Ben J. Yorks, Reg. No. 33,609; and Norman Zafman, Reg. No. 26,250; my attorneys; and Amy M. Armstrong, Reg. No. P42,265; Robert Andrew Diehl, Reg. No. P40,992; and Edwin A. Sloane, Reg. No. 34,728; my patent agents, with offices located at 12400 Wilshire Boulevard, 7th Floor, Los Angeles, California 90025, telephone (714) 557-3800, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole/First Inventor (given name, family name) Hai Bui

Inventor's Signature  Date 5/21/99

Residence Fountain Valley, California USA Citizenship USA
(City, State) (Country)

P. O. Address 9426 Kiwi Circle
Fountain Valley, California 92708 USA